

### REMARKS

This amendment and reply is in response to the Office Action dated March 6, 2007. Applicant has amended independent claim 26. Support for the amendment can be found, for example, at paragraphs 14 and 34 of U.S. Patent Application Publication No. US 2004/00191443, the published application to Application No. 10/822,182. No new matter is added. In amending the claims Applicant does not concede that the claims as originally presented or previously amended are unpatentable over the references cited in the Office Action and reserves the right to pursue the previously presented claims in one or more continued applications. Applicant thanks the Examiner for the withdrawal of the rejections under 35 U.S.C. § 112 ¶1. Claims 26-29, 32 and 33 are presented for examination. In view of the foregoing amendment and following remarks, Applicant requests entry of the claim amendments and reconsideration and withdrawal of the rejections.

### Priority

Applicant notes the Examiner's comments with regard to Applicant's claim of priority in the present application. Amendment of the claims is made without acquiescing in the Examiner's conclusions or comments with regard to priority.

### Rejections for Double Patenting

Claims 26-29, 32 and 33 are provisionally rejected under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-30, 33 and 34 of copending Application No. 10/839,687 in view of U.S. Patent No. 4,799,717 (Kingsford). Applicant does not necessarily agree with this rejection, but to obviate the rejection, Applicant may submit an appropriate terminal disclaimer upon the indication that the claims are otherwise allowable. A terminal disclaimer (unsigned) of suitable form is attached.

Rejections Under 35 U.S.C. § 102

Claims 26-29, 32 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 90/15706 (Harvey). Independent claim 26, as amended, recites a method of producing a laminated expander member by, *inter alia*, forming a multilayer parison comprising a first layer including a liquid crystal polymer, and a second layer, internal to the first layer, the second layer being an adhesion layer for bonding the expander member to the exterior of a catheter tube, and forming the parison into the expander member. Harvey, however, does not disclose or suggest each of the limitations of claim 26. For the Examiner's convenience, citations to Harvey are taken from U.S. Patent 5,288,529.

The Examiner argues that Harvey teaches a method of producing a laminated expander member/tube and forming a parison into the expander member/tube. Applicant respectfully disagrees. Harvey is directed to the formation of a liquid crystal polymer film, and "in particular a film which will lie flat." (Harvey, col. 4, lines 15-20). Nowhere does Harvey teach or disclose a method of forming the extruded film disclosed in Harvey into an expander member or expandable portion of a balloon catheter.

The Examiner also argues that the co-extruded layers of the tube are laminated/adhere to each other and, therefore, meets the limitation that the second layer is an adhesion layer. Applicant respectfully disagrees, but in the interest of furthering prosecution, Applicant has amended claim 26 to include the limitation that the adhesion layer bonds the expander member to the exterior of a catheter tube. The present application specifically provides that the tensile layer is combined as an outer layer with a compatible adhesion or bonding layer, and this adhesion or bonding layer "imparts the necessary adhesion properties to properly bond the expander member to the distal end portion of the catheter body." (U.S. 2004/0191443 at ¶ 14). And that the "inner layer can be caused to adhere to and attach the balloon to the exterior of the tubular catheter body." (U.S. 2004/0191443 at ¶ 34). Harvey does not disclose or suggest an adhesion layer for bonding an expander member to a catheter tube.

Claims 27-29, 32, and 33 are dependent on claim 26 and should be allowable for at least the same reasons as discussed above. Applicants request that the rejection be withdrawn.

Claims 26-29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,248,305 (Zdrahala). As previously mentioned, independent claim 26, as amended, recites a method of producing a laminated expander member by, *inter alia*, forming a multilayer parison comprising a first layer including a liquid crystal polymer, and a second layer, internal to the first layer, the second layer being an adhesion layer for bonding the expander member to the exterior of a catheter tube, and forming the parison into the expander member.

Zdrahala, however, does not disclose or suggest each element of claim 26 as amended. Specifically, Zdrahala does not disclose the formation of an expander member, nor does Zdrahala disclose an adhesion layer for adhering the expander member to the exterior of a catheter tube. Instead, Zdrahala is directed to a stiffened, steerable catheter. (Zdrahala, col. 8, lines 14-25). Nowhere does Zdrahala discuss formation of an expansion member on a catheter. Moreover, Zdrahala discusses the use of polyurethanes, hydrophilic polyurethanes, urethane-silicone blends, urethane fluoropolymer copolymers, vinyl polymers, acrylates or other bio/hemocompatible polymers as lubricious coatings. (Zdrahala, col. 4, lines 34-50). But Zdrahala does not teach the use of such coatings as adhesion layers for bonding an expansion member to a catheter tube. As such, Zdrahala does not disclose the claimed subject matter.

Claims 27-29, and 32 are dependent on claim 26, as amended, and should be allowable for at least the same reasons as discussed above. Applicant requests the rejection be withdrawn.

#### Rejections Under 35 U.S.C. § 103

Claims 33 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Zdrahala in view of either U.S. Patent 4,490,421 (Levy) or U.S. Patent No. 5,041,125 (Montano). Claim 33 is dependent on claim 26 and further requires forming the parison into the expander member by drawing the parison and expanding the parison in a blow molding operation. As previously discussed, Zdrahala does not disclose forming an expander member nor does Zdrahala disclose an adhesion layer for bonding the expander member to the catheter tube. Either Levy or Montano, considered individually or together do not cure this deficiency. Levy is directed to a blow molding process for manufacturing a balloon but does not disclose or suggest a multilayer

co-extruded balloon or expander member having an adhesion layer for bonding the expander member to the catheter tube. (Levy, col. 3: line 63 through col. 4: line 49). Montano is directed to a catheter body having an inflatable balloon configured to facilitate folding. Montano discloses that the catheter balloon may be made of any conventional material and molded in a conventional blow molding process. (Montano, col. 2, lines 29-37). As such, Zdrahala in view of either Levy or Montano do not disclose the claimed subject matter as amended. Applicant requests the rejection be withdrawn.

#### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

For at least the reasons discussed above, Applicants believe the claims are in condition for allowance, which action is requested.

Please apply any other charges or credits to deposit account 06-1050.

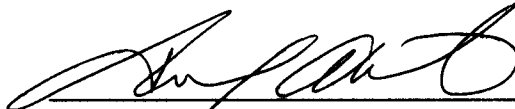
Applicant : Robert N. Hamlin  
Serial No. : 10/822,182  
Filed : April 9, 2004  
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Attorney's Docket No.: 10527-003008 / PC7558G-US

Respectfully submitted,

Date:

September 6, 2007



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Robert N. Hamlin	Art Unit	: 1732
Serial No.	: 10/822,182	Examiner	: Jeffrey Michael Wollschlager
Filed	: April 9, 2004	Conf. No.	: 1770
Title	: MULTILAYER CATHETER BALLOON		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TERMINAL DISCLAIMER UNDER 37 C.F.R. §§ 3.73(b) AND 1.321(b)

Pursuant to 37 C.F.R. § 3.73(b), SCHNEIDER (USA) INC., a corporation, certifies that it is the assignee of the entire right, title, and interest in the above-referenced application by virtue of an assignment from the inventors of the above-referenced patent application. The assignment was recorded in the Patent and Trademark Office at Reel 5776, Frame 0360 on July 9, 1991, or a copy thereof is attached. To the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned is empowered to act on behalf of the assignee.

Pursuant to 37 C.F.R. § 1.321(b), and to obviate a double patenting rejection, the assignee identified above hereby waives and disclaims the terminal portion of the term of the entire patent to be granted upon the above-referenced application subsequent to the expiration date of the patent to issue from U.S. Application Serial No. 10/839,687, provided that any patent granted on the above-referenced application shall be enforceable only for and during such period that it is commonly owned with the patent to issue from U.S. Application Serial No. 10/839,687.

The assignee identified above does not disclaim any terminal part of any patent granted on the above-referenced application prior to the expiration date of the full statutory term of the patent to issue from U.S. Application Serial No. 10/839,687, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321(a), has all claims cancelled by a reexamination certificate, or is otherwise terminated prior to expiration of its statutory term, except for the separation of legal title as stated above. Assignee herein does not disclaim or otherwise affect any part of the patent to issue from U.S. Application Serial No. 10/839,687.

Applicant : Robert N. Hamlin  
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This disclaimer runs with any patent granted on the above application and is binding upon the grantee, its successors or assigns.

The required fee in the amount of \$130 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: September 6, 2007

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